

## EXHIBIT 402



# **DEA Suspicious Orders: Recommended Industry Compliance Guidelines**

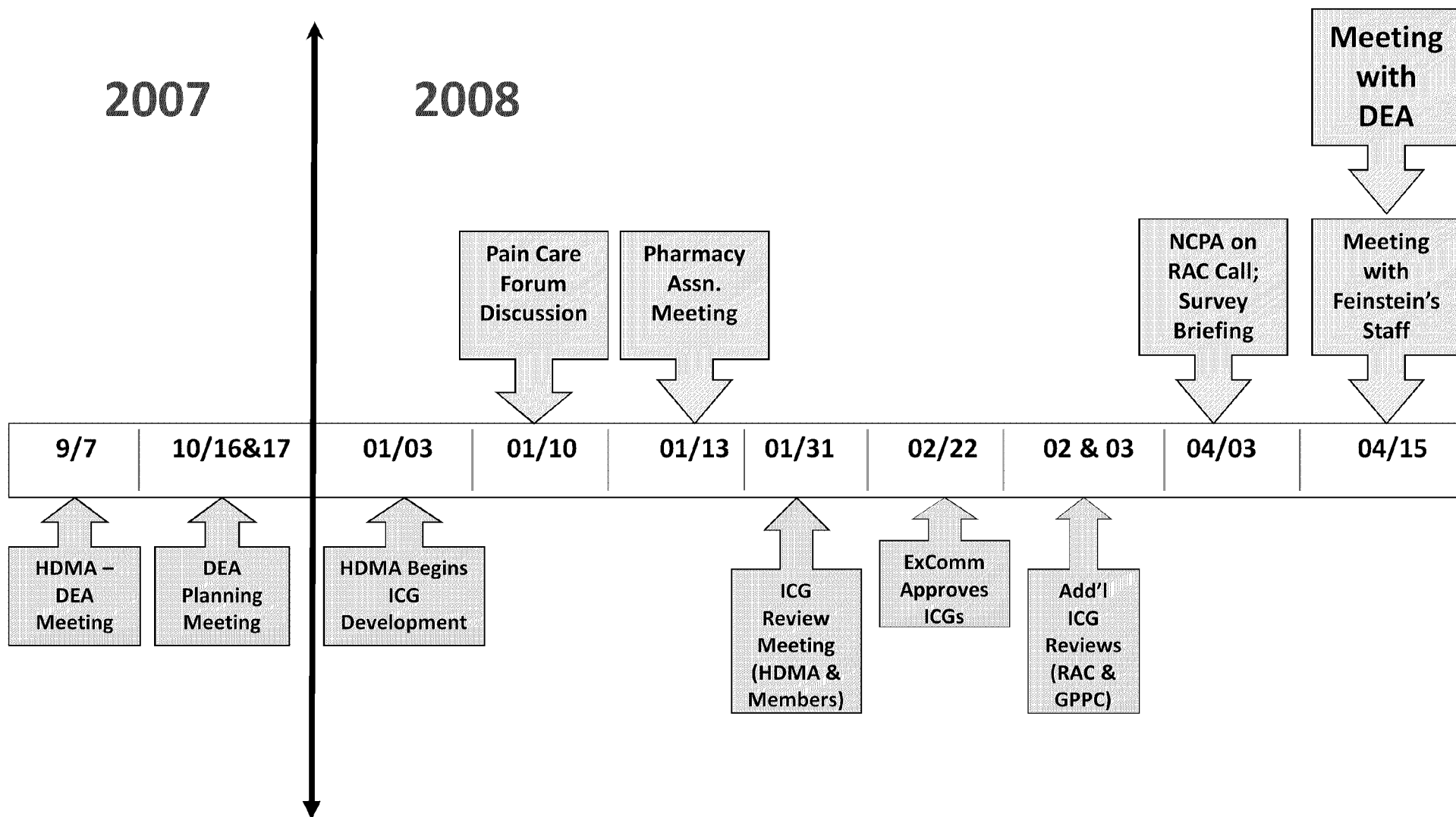
Regional Roundtable

May 7, 2008

# Today's Agenda

- Background/Overview
- Rationale for “Industry Compliance Guidelines” (ICGs)
- Process for Development
- Describe ICGs
- DEA Meeting Summary
- Next Steps
- Other DEA Issues

# Development of the ICGs



# Industry Compliance Guidelines At a Glance

## Introduction

### **I. Know Your Customer**

- Info Gathering, review, investigation

### **II. SO Monitoring**

- System design
- i.d. product/customer characteristics for “Thresholds”
- Cumulative reviews
- Stop shipments

### **III. Investigation of Orders of Interest**

- Initial Review, Investigating further, documentation, shipment and reporting, future customer orders

# **Industry Compliance Guidelines At a Glance (Cont'd)**

## **IV. File Suspicious Order Reports**

- Immediate reporting
- Correspondence
- Documentation

## **V. Employees, Training and SOPs**

## **VI. Additional Recommendations**

# April 15 Presentation to DEA

- Purpose: Demonstrate Industry Commitment
  - Clarify requirements for distributors
  - Making tangible efforts
  - Hopefully, receive DEA “Imprimatur”
- Reviewed the ICGs
- Described anticipated “launch” activities, e.g.,
  - Public availability & announcement(s)
  - Education - HDMA members, pharmacists
  - Outreach - Allied trade associations, Pain Care Forum
  - The Hill

# DEA Reaction

- Only one question: *Please clarify “what is stopped”* [when a threshold is exceeded]?
- Gleason pleased
  - DEA “welcomes the dialogue”
  - Agreed to meet again after review
- Little additional reaction

# Next Steps

- DEA requested a follow-up meeting
  - Date TBD
  - HDMA suggested week of May 12
- HDMA will
  - Review DEA reaction with appropriate committees
  - Further HDMA action/reaction depends on DEA and Committee input

# Additional DEA Activities

- In-Transit Losses
- Iodine
- Methadone
- 2 Proposed Rules
  - Form 222
  - Self-Certification Numbers
- Meeting with Mark Caverly

